ORIGINAL

Elizabeth J. Cabraser (State Bar No. 083151)
ecabraser@lchb.com
Wendy R. Fleishman
wfleishman@lchb.com
LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
Embarcadero Center West
275 Battery Street, 30th Floor
San Francisco, CA 94111-3339
Telephone: (415) 956-1000
Facsimile: (415) 956-1008

Attorneys for Plaintiff

[Additional Counsel On Signature Page]

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO / OAKLAND DIVISION

BZ

RASHID HUNTER, individually and on behalf of all others similarly situated,

Plaintiff,

v.

MEDTRONIC, INC., MEDTRONIC INTERNATIONAL TECHNOLOGY, INC. formerly known as MEDTRONIC PUERTO RICO, INC., and MEDTRONIC PUERTO RICO OPERATIONS CO.,

Defendants.

Case No.

CLASS ACTION COMPLAINT FOR DECLARATORY, INJUNCTIVE AND EQUITABLE RELIEF AND DAMAGES

DEMAND FOR JURY TRIAL

Plaintiff Rashid Hunter, by his undersigned counsel, individually and for all other residents and citizens of the State of California who are similarly situated, hereby commences this individual and Class Action against Medtronic, Inc., Medtronic International Technology, Inc. formerly known as Medtronic Puerto Rico, Inc. and Medtronic Puerto Rico Operations Co. (hereinafter collectively "Defendants" or "Medtronic," unless otherwise stated) for compensatory, equitable, injunctive, and declaratory relief. Plaintiff makes the following allegations based upon his personal knowledge as to his own acts, and upon information and belief, as well as upon his

attorneys' investigative efforts as to Medtronic's actions and misconduct, and alleges as follows:

PARTIES

1. Individual and representative Plaintiff Rashid Hunter is a citizen and resident of the County of Alameda in the State of California.

2. Defendant Medtronic, Inc., is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Medtronic develops technology to treat conditions such as heart disease and other illnesses. Medtronic manufactures medical devices and sells them worldwide. Medtronic's Cardiac Rhythm Disease Management Division ("CRM Division") is the division that develops, researches, advertises, promotes, markets and sells all of Medtronic implantable defibrillators ("ICDs"), and leads, some of which are marketed under the trade name "Sprint Fidelis." CRM Division's operations are principally conducted out of its facilities at Cardiac Rhythm Disease Management at 7000 Central Ave., Minneapolis, Minnesota 55432.

3. Defendant Medtronic International Technology, Inc., formerly known as Medtronic Puerto Rico, Inc., is a corporation existing by virtue of the laws of the Territory of Puerto Rico, with its principal place of business at Road 149, km 56.3, Box 6001 Villalba, PR.

4. Defendant Medtronic Puerto Rico Operations Co., is a corporation existing by virtue of the laws of the Territory of Puerto Rico, with its principal place of business at Road 149, km 56.3, Box 6001 Villalba, PR.

5. Medtronic International Technology, Inc., and Medtronic Puerto Rico Operations Co., are wholly owned subsidiaries of Medtronic, Inc., which formulate, develop, manufacture and sterilize the devices at issue in this lawsuit.

INTRODUCTION

6. Medtronic designs, researches, develops, manufactures, tests, markets, advertises, promotes, distributes, and sells products that treat cardiac arrhythmias, heart failure, and coronary and peripheral vascular disease. An arrhythmia is an irregular cardiac rhythm, which can cause significantly decreased cardiac output and ultimately, death. Medtronic holds itself out as "the global leader in medical technology, alleviating pain, restoring health and

extending life for millions of people around the world." *See* 2005 Annual Statement, Medtronic, Inc.

7. A number of devices designed to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms are available from Medtronic and other manufacturers, including implantable cardiac defibrillators ("ICDs"). ICDs contain pacemakers as well as defibrillators; while a pacemaker is used primarily to correct slow heart rates, an ICD detects and corrects both fast and slow heart rates. The pacemaker portion corrects the slow rates and the anti-tachycardia portion can "over-drive pace" rapid rates. The defibrillator portion can shock ventricular tachycardia and ventricular fibrillation to stop the heart and allow an appropriate rhythm to take over.

8. ICDs are designed to be implanted primarily under the skin of the chest wall. The device's power source, or pulse generator, is implanted in a pouch formed in the chest wall generally over the left pectoralis major muscle.

9. Typically, wires called leads are inserted through a major vein and attached directly to the muscle on the inside of the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and can administer an electric shock to abort a dangerous "over-drive pace," a very rapid rhythm, or pace the heart at a normal rhythm if an irregularity is detected.

10. Such devices are used in patients, like Plaintiff Rashid Hunter and the Class members (hereinafter "Plaintiff" and "Class members"), who have arrhythmias or irregular heartbeats that are considered life-threatening. The Class members with these medical problems include patients who are at risk for ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart), and ventricular tachycardia (excessively rapid heartbeat) that are poorly controlled by medication. These arrhythmias or irregular heart beats can result in the loss of consciousness or death, unless the patient receives therapy from an appropriate device to put the heart back into an appropriate cardiac rhythm.

11. If an implanted ICD and lead operate properly, the system can save a patient's life. If either fails to operate, the patient may die within minutes.

THE SPRINT FIDELIS LEADS

12. This Class Action seeks recovery for residents and citizens of the State of California who are patients who have been implanted with Sprint Fidelis leads marketed by Medtronic under the following model numbers:

(i) the 6949 LFJ extendable/retractable screw fixation (S) model;

(ii) the 6948 LFH tuned fixation (T) model;

(iii) the 6931 LFT S fixation; and

(iv) the 6930 LFK T fixation.

13. At all times relevant, these Sprint Fidelis leads were researched, developed, manufactured, marketed, promoted, advertised, sold, and distributed by Medtronic to be used in connection with ICDs.

14. The majority of ICDs now use two or three leads. As a result, smaller high-voltage leads are attractive to electrophysiologists because they are believed to be easier to insert, and are less likely to obstruct blood flow or distort the tricuspid valve. The Medtronic Sprint Fidelis leads are smaller high voltage leads.

15. In 2001, Medtronic marketed its then-smallest defibrillation lead called the Sprint Quattro Secure, model 6947 ("Quattro leads").

16. In 2004, Medtronic introduced and marketed the Sprint Fidelis to replace the Sprint Quattro as the high voltage lead of choice and to attempt to gain a larger market share.

17. At the time that Medtronic announced the marketing of the Sprint Fidelis leads, Medtronic claimed that "[t]he small size of the Sprint Fidelis (Fidelis is a Latin word that means 'faithful') helps improve passage into a patient's venous system for an easier implant, and minimizes venous obstruction." Medtronic also referred to the leads as "state-of-the-art." *See* Medtronic News Release (Sept. 2, 2004), available at http://wwwp.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1095281834568&lang=en_US.

18. Medtronic further represented that the Sprint Fidelis leads were based on the "proven" design of the Quattro leads.

19. The Sprint Fidelis leads were approved for sale by the United States Food and Drug Administration (the "FDA") in September 2004 and have been implanted in over 160,000 patients worldwide.

20. The Sprint Fidelis lead is a 6.6 French[1] isodiametric multifilar true bipolar high voltage lead with silicone insulation and polyurethane outer coating.

21. The Models 6949 and 6948 have two high voltage coils; the 6930 and 6931 models have a single right ventricular high voltage coil. As of January 2007, at least 144,311 model 6949 Sprint Fidelis leads, 7510 model 6948 leads, 5387 model 6931 leads, and 236 model 6930 leads had been implanted.

THE DEFECTS IN THE SPRINT FIDELIS LEADS

22. Since the Sprint Fidelis leads were introduced to the market, it has become evident that a significant portion of the leads have potentially fatal defects.

23. Such defects were discussed in an article written by doctors at The Minneapolis Heart Institute, one of the premiere heart institutes in the world, based on a study of the incidence of lead failures in the Sprint Fidelis models compared to the Sprint Quattro models. According to the report, which was prepared by Dr. Robert G. Hauser, *et al.*, and published in the Heart Rhythm Society Journal in the Spring of 2007, "Early Failure of Small-Diameter High-Voltage Inflammable Cardioverter-Defibrillator Lead," Heart Rhythm Society 2007.03.041 (2007) ("Early Failure"), the Minneapolis Heart Institute's experience reflected that, between September 2004 and February 2007, 583 patients were implanted with Sprint Fidelis Model 6949 leads, and nine patients received other Sprint Fidelis models. During that time, six patients experienced Sprint Fidelis Model 6949 lead failures. The failed Sprint Fidelis Model 6949 leads had been implanted by various electrophysiologists, cardiologists and thoracic surgeons. The average time to failure was fourteen months (based on a range of four to twenty-three months). *Early Failure*, p. 893.

[1] French is a measure of circumference in this instance. One French is equal to 0.33 mm, or approximately 0.012 inches.

24. The study compared the actuarial survival of the 583 Sprint Fidelis Model 6949 leads implanted at the Minneapolis Heart Institute to the survival of 285 Sprint Quattro Model 6947 leads implanted at the Institute between November 2001 and March 2007. The difference in survival between the Sprint Fidelis Model 6949 lead and the Sprint Quattro Secure Model 6947 lead was extremely significant. The failure rate for the Sprint Fidelis Model 6949 lead was 1-2% during the first two years of implant and was ten times greater than the failure rate for the Sprint Quattro Secure Model 6947 lead. *Early Failure*, p. 893-894

25. The significant number of lead failures involved lead fractures of the PACE-sense conductor or coil in the Sprint Fidelis Model 6949. The fracture rate for the Sprint Fidelis leads was three times higher than the fracture rate of the Quattro Model 6947. *Early Failure*, p. 894-895.

26. Another study, conducted at Cornell University Medical Center by Sunil Mirchandani, *et al.*, found "(a) 17% incidence of abnormal right ventricular sensing during follow-up of patients implanted with the Medtronic Sprint Fidelis ICD lead," necessitating "an early revision of the system in 4% of patients." *See* Abstract of *Defibrillator Leads: Is Smaller Necessarily Better?*, 2006, available at http://vivo.library.cornell.edu/entity.

27. Medtronic has not disclosed the precise mechanism of the Sprint Fidelis lead fracture failures. However, it appears that the defect in the Sprint Fidelis may be attributable to the small diameter of the coil and conductors and the fact that, in light of this small diameter, it is subject to stress damage both during and after implant. Fracture eventually occurs when the conductor is critically overstressed. The number of fractures that have been observed in these leads indicates that there is a clear defect in the leads themselves, and that defect was demonstrated in the Model 6949 Sprint Fidelis leads that were implanted in Plaintiff Rashid Hunter. Further, Plaintiff Rashid Hunter and Class members who, like Plaintiff Mr. Hunter were implanted with Sprint Fidelis leads, require ongoing and expensive medical monitoring of their Sprint Fidelis leads.

28. A review of the FDA's MAUDE database, which contains reports of adverse events associated with the use of medical devices, discloses that, as of July 2007, over

1000 Medical Device Reports ("MDRs) regarding Sprint Fidelis leads had been filed since September 2004. The most frequent complaints were fractures and inappropriate shocks, and the most common observations were high impedance, oversensing and noise, and failure to capture or high threshold.

29. Medtronic analyzed approximately 125 of those leads that were returned to Medtronic before July 2006. According to the relevant MDR reports, Medtronic concluded that 77 out of 125 leads (or 62%) were defective. The predominant manifestation of the defect was conductor fracture, involving the PACE-sense conductor and coil or the high voltage (defibrillation) conductor. PACE-sense conductor or coil fracture was manifested by inappropriate shocks or oversensing/noise and high impedance, while high voltage conductor fracture was primarily linked to high impedance

30. Medtronic filed more than 350 additional MDRs regarding the Sprint Fidelis leads between August 2006 and February 2007. Medtronic did not include similar analysis of those leads in the MDRs filed by Medtronic during this period.

31. On March 21, 2007, Medtronic issued a physician advisory, in the nature of a "Dear Doctor Letter," that advised physicians of "the higher than expected conductor fracture rates in … Sprint Fidelis leads." Medtronic claims in that letter to be investigating reports of lead failures, however, still represents that the Sprint Fidelis leads are performing consistent with, and "in line with other Medtronic leads …. And consistent with lead performance publicly reported by other manufacturers." This letter also states, "…variables within the implant procedure may contribute significantly to these fractures… For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area." At no time prior to this letter did Medtronic warn physicians that its leads must be specially handled during the implantation procedure or that they could "severely bend" or "kink" if they are implanted using certain accepted implant techniques.

32. On October 15, 2007, Medtronic voluntarily withdrew all unimplanted Sprint Fidelis leads from the U.S. market, citing several deaths related to the leads. Medtronic

stated that approximately 268,000 Sprint Fidelis leads have been implanted worldwide. Medtronic recommended that implanted Sprint Fidelis leads be monitored and reprogrammed.

33. Medtronic has recommended medical monitoring and reprogramming of the ICDs to monitor the Sprint Fidelis leads, according to an article in the October 15, 2007 *Wall Street Journal*, "Medtronic Pulls Defibrillator Wires Off Market."

34. Medtronic's representation of the consistency of the performance of the Sprint Fidelis leads is untrue in light of the reported experience with the leads and the various issues included in the MAUDE database reports.

35. At all times relevant, Medtronic misrepresented the safety of the Sprint Fidelis leads and negligently manufactured, marketed, advertised, promoted, sold, and distributed the leads as safe devices to be used together with ICDs for prophylactic treatment of patients with prior myocardial infarction and decreased ejection fraction, ventricular arrhythmias, and patients who are at high risk for developing such arrhythmias. Some patients are dependent on such devices to maintain an appropriate heart rhythm, and therefore, adequate cardiac output. For these patients, failure of the leads connected to the ICD can cause sudden faintness, or loss of consciousness, and can result in death.

36. At all times relevant, Medtronic failed to warn that the Sprint Fidelis leads were prone to breakage or that particular processes should be implemented in order to avoid breaking the Sprint Fidelis leads.

37. As a result of their defective design and manufacture, Medtronic's Sprint Fidelis leads suffer fracture, leading to malfunction in the transmission of the electric signal from the ICD to the patient's heart.

38. At all times relevant, the Sprint Fidelis leads (collectively the "leads") were researched, developed, manufactured, marketed, promoted, advertised and sold by Medtronic.

39. At all times relevant, Medtronic misrepresented the safety of the Sprint Fidelis leads, and negligently manufactured, marketed, advertised, promoted, sold and distributed the leads as safe and effective devices to be used for implantation with ICDs for prophylactic treatment of patients with prior myocardial infarction and a limited ejection fraction, patients who

have had spontaneous and/or inducible life-threatening ventricular arrhythmias, and patients who are at high risk for developing such arrhythmias.

40. At all times relevant, Medtronic knew, and had reason to know, that the Sprint Fidelis leads were not safe for the patients for whom they were prescribed and implanted, because the leads fractured and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in some patients, catastrophic injuries and deaths.

41. At all times relevant, Medtronic knew, and had reason to know, that its representations that the Sprint Fidelis leads were easier to implant and based on "proven" technology were materially false and misleading.

42. As a result of this defective design and manufacture, the leads can cause serious physical trauma and/or death. Medtronic knew and had reason to know of this tendency and the resulting risk of injuries and deaths, but concealed this information and did not warn Plaintiff, the Class members or their physicians, preventing Plaintiff, the Class members and their physicians, and the medical community from making informed choices about the selection and use of particular defibrillator leads for implantation.

43. Approximately 268,000 of the affected devices remain in service in the United States and in other countries.

44. Medtronic has records of all patients with implanted leads, and can identify all members of the class of California state residents and citizens with implanted and defective leads who require medical monitoring.

45. The information Medtronic has made available to patients and their doctors about the need for medical monitoring, the types of available monitoring, and the costs incident to such monitoring are extremely inconsistent and confusing.

46. Plaintiff seeks implementation of a medical monitoring program to be administered by this Court, which will afford each California state lead recipient with consistent monitoring paid for by Defendants.

47. Plaintiff now brings this action to seek injunctive relief or an expedited trial pursuant to Rule 65 of the Federal Rules of Civil procedure to adjudicate his claims against Medtronic and to implement a medical monitoring program immediately.

JURISDICTION AND VENUE

48. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) because this action is a class action that includes parties and Class members who are citizens of different states and the matter in controversy exceeds the sum or value of $5,000,000 exclusive of interest and costs.

49. Venue is proper under 28 U.S.C. §§ 1391 (a) and (c). Medtronic earns substantial compensation and profits from sales of Sprint Fidelis leads in this District.

INTRADISTRICT ASSIGNMENT

50. Assignment of this matter to the San Francisco/Oakland Division of this Court is proper pursuant to L.R. 3-2(c) and (d), because Mr. Hunter resides in Alameda County and the action arises in Alameda County.

CLASS ACTION ALLEGATIONS

51. Plaintiff brings this action on behalf of himself and all others similarly situated, as members of a proposed Plaintiff class (the "Class") of all individuals who have been implanted with the leads at issue, and propose a California Class, composed of:

> All citizens and residents of the State of California who have been implanted with Sprint Fidelis leads marketed by Medtronic under the following model numbers: (1) the 6949 LFJ extendable/retractable screw fixation (S) model; (2) the 6948 LFH tuned fixation (T) model; (3) the 6931 LFT S fixation; and (4) the 6930 LFK T fixation, manufactured by Medtronic ("patient recipients"), during the period from January 1, 2004 through the present (the "Class period"), and their legal guardians or representatives.

52. Excluded from the proposed subclass are (i) Medtronic, any entity in which Medtronic has a controlling interest or which have a controlling interest in Medtronic, and Medtronic's legal representatives, predecessors, successors and assigns; (ii) the judicial officers to whom this case is assigned; and (iii) any member of the immediate families of excluded persons.

53. The Class is so numerous that the individual joinder of all its members is impracticable. While the exact number and identification of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery of Medtronic, Plaintiff is informed and believes that the Class includes thousands of patient recipients statewide.

54. This action is brought and may properly be maintained as a class action pursuant to the provisions of Federal Rule of Civil Procedure 23(a)(1)-(4), 23(b)(2), and 23(b)(3) and/or 23(c)(4)(A). This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions. Common questions of fact and law exist as to all Class members which predominate over any questions affecting only individual Class members. These common legal and factual questions, which do not vary from Class member to Class member, and which may be determined without reference to the individual circumstances of any Class member, include, but are not limited to, the following:

(a) Whether there are design and/or manufacturing defects in Medtronic's Sprint Fidelis leads;

(b) Whether Medtronic failed to follow United States Food & Drug Administration ("FDA") good manufacturing practices, failed to properly investigate manifestations of the lead defects over the past several years, failed to adequately document reports of the defects, and failed to exercise adequate quality control;

(c) Whether Medtronic's conduct in designing, manufacturing, marketing, and monitoring the Sprint Fidelis leads fell below the duty of care owed by Medtronic to Plaintiff and the other Class members;

(d) Whether Medtronic intentionally, deliberately, uniformly, knowingly, carelessly, recklessly, or negligently misrepresented, omitted, concealed and suppressed material and important information regarding the existence of a defect in the Sprint Fidelis leads from Plaintiff, the FDA, physicians and Class members;

(e) Whether the Sprint Fidelis leads listed in the proposed Class definition share common and inherent design and manufacturing defects that cause them to fracture and malfunction, causing inappropriate shocks and failure to deliver an effective shock when needed, creating a risk of injury or death to patients in whom they were implanted;

(f) Whether Medtronic negligently, intentionally, deliberately, uniformly, or recklessly materially misrepresented, concealed, omitted, or suppressed the quality and usefulness of the leads, thereby inducing Plaintiff and the Class to accept implantation of the Sprint Fidelis leads rather than another brand of leads, which would not have been prone to the defects;

(g) Whether Medtronic is liable for selling a dangerously defective product;

(h) Whether Medtronic failed to adequately warn or notify patient recipients, the medical community, and the regulators of the defect, dangers, disadvantages and hazards of the leads;

(i) Whether Medtronic failed to adequately warn or notify hospitals and physicians regarding the defect, malfunction and/or hazards of the defective leads;

(j) Whether Medtronic breached express or implied warranties;

(k) Whether Medtronic's conduct constitutes negligence;

(l) Whether Medtronic is liable for negligent infliction of emotional distress;

(m) Whether Medtronic's misconduct violated applicable consumer protection statutes;

(n) Whether Plaintiff and Class members are entitled to injunctive and other equitable relief, including restitution and disgorgement, and if so, the nature of such relief;

(o) Whether Plaintiff and Class members are entitled to medical monitoring, reprogramming, surveillance and medical treatment at Medtronic's expense;

(p) Whether Medtronic is liable for punitive or exemplary damages, and if so, the amount necessary and appropriate to punish them for their conduct, to deter others, and to fulfill the other policies and purposes of punitive and exemplary damages; and,

(q) Which mechanism, among the methods available under the Federal Rules of Civil Procedure, is superior to ensure the fair and efficient adjudication of this controversy within the meaning of Fed. R. Civ. P. 23(b)(3).

55. Plaintiff's claims are typical of the claims of the Class members. Plaintiff and other Class members must prove the same facts in order to establish the same claims, described herein, which apply to all Class members.

56. Plaintiff is an adequate representative of the Class because he is a member of the Class and his interests do not conflict with the interests of the Class members he seeks to represent. Plaintiff has retained counsel competent and experienced in the prosecution of products liability, mass torts, and consumer fraud class actions, and together Plaintiff and counsel intend to prosecute this action vigorously for the benefit of the Class. The interests of Class members will fairly and adequately be protected by Plaintiff and their counsel.

57. A class action is superior to other available methods for the fair and efficient adjudication of this litigation since individual litigation of the claims of all Class members is impracticable. Even if every Class member could afford individual litigation, the court system could not. It would be unduly burdensome to the courts, in which individual litigation of thousands of cases would proceed. Individual litigation presents a potential for inconsistent or contradictory judgments, the prospect of a race for the courthouse, and an inequitable allocation of recovery among those with equally meritorious claims. Individual litigation increases the expense and delay to all parties and the court system in resolving the legal and factual issues common to all Medtronic Sprint Fidelis lead claims. By contrast, the class action device presents far fewer management difficulties and provides the benefit of a single adjudication, economies of scale, and comprehensive supervision by a single court.

58. The various claims asserted in this action are additionally or alternatively certifiable under the provisions of Federal Rules of Civil Procedure 23(b)(1) and/or 23(b)(2) because:

(a) The prosecution of separate actions by thousands of individual Class members would create a risk of inconsistent or varying adjudications with respect to individual Class members, thus establishing incompatible standards of conduct for Medtronic;

(b) The prosecution of separate actions by individual Class members would also create the risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of the other Class members who are not a party to such adjudications and would substantially impair or impede the ability of such non-party Class members to protect their interests;

(c) Medtronic has acted or refused to act on grounds generally applicable to the entire Class, thereby making appropriate final declaratory and injunctive relief with respect to the Class as a whole.

ALLEGATIONS

59. Medtronic designed, manufactured, marketed, promoted, sold, and distributed four (4) models of defective leads, including: (1) the Sprint Fidelis 6949 LFJ extendable/retractable screw fixation (S) model; (2) the 6948 LFH tuned fixation (T) model; (3) the 6931 LFT S fixation model; and (4) the 6930 LFK fixation (T) model. All of the these models contain the same defect.

60. The Sprint Fidelis leads were originally approved for sale by the FDA in September 2004.

61. The Sprint Fidelis leads are uniformly defective in that they are prone to fracture of the PACE-sense conductor and coil and the HV conductor, causing them to fail to function in a manner which may not be immediately detectable by the patient. The

malfunctioning can lead to terrifying inappropriate defibrillation shocks, failure to deliver appropriate (life-giving) defibrillation therapy and death.

62. There is no test that predicts whether the Sprint Fidelis leads will fail.

63. To this day, Medtronic has refused to suggest replacement of the defective Sprint Fidelis leads in its patients, even though emergency replacement of the leads is required in patients in whom these defects have been discovered.

A. Medtronic's Concealment of the Defects

64. Medtronic's failure to document or follow up on the known defects in its Sprint Fidelis leads, and concealment of known defects from the FDA, Plaintiff, the medical community and Class members constitutes fraudulent concealment that equitably tolls any applicable statute of limitation.

65. No member of the Class could have discovered the existence of the defect in the Sprint Fidelis leads until at least March 2007, when the first physician advisory was sent by Medtronic to physicians concerning the fragile nature of these leads.

66. Medtronic is estopped from relying on the statute of limitations as a defense because Medtronic actively concealed the lead defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians or Class members. Instead of revealing the defects, Medtronic continued to represent its products as safe for their intended use.

67. Medtronic's conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Medtronic must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff and Class members.

B. Medtronic's Failure to Provide Adequate and Accurate Information

68. Thousands of patients' lives rely upon the proper functioning of these Sprint Fidelis leads, and they — along with their physicians — have been vigorously attempting to assess the risks that they now face.

69. Patients and physicians remain uninformed and confused about whether the devices should be removed, or even whether all of the defects have been disclosed.

70. Because of incomplete, inconsistent, and/or confusing information published by Medtronic, it remains unclear how many patients are affected by these defective leads. Although, based on the population of Medtronic patients whose claims are asserted in this Complaint, it is likely to be thousands of heart patients in the State of California.

C. Corporate Liability

71. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to Plaintiff.

72. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

73. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's damages.

74. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and

promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

D. Medical Monitoring

75. On October 15, 2007, Medtronic publicly advised all patients with their leads that medical monitoring of their leads was advisable.

76. On October 22, 2007, Medtronic sent form letters to each of the patients and Class members with defective leads. To date, Medtronic sent letters to 175,000 patients with Sprint Fidelis leads and the hospitals and doctors, who had implanted these leads. In those letters, Medtronic advised patients, like Mr. Hunter, to seek advice from their physicians so that their devices could be monitored and reprogrammed. The information made available to Mr. Hunter and others Class members is, however, both confusing and frightening, because the failure of the leads is not predictable.

PLAINTIFF

77. Plaintiff Rashid Hunter has a cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. Mr. Hunter was implanted with a cardiac pacemaker/defibrillator combination (an "ICD") on January 17, 2005, at Washington Hospital Healthcare System in Fremont, California. The ICD was attached to his heart with a lead wire system called a Sprint Fidelis lead, model number 6949, manufactured by Medtronic.

78. As a result of the Medtronic advisory, it is clear that Mr. Hunter's 6949 must be closely monitored.

79. Mr. Hunter has suffered and will continue to suffer severe emotional damages and has incurred, and will in the future continue to incur medical expenses and losses, including the need for an expense of ongoing medical monitoring, as a result of Medtronic's wrongful conduct.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
(Products Liability)

80. Plaintiff, on behalf of himself and all others similarly situated, re-alleges and incorporates the allegations contained in the foregoing paragraphs.

81. At all relevant times hereto, Medtronic was engaged in the business of designing, manufacturing, assembling, promoting, advertising, selling, and distributing the Sprint Fidelis leads for ultimate sale to, and implantation in, heart disease/disorder patients. Medtronic designed, manufactured, assembled, and sold the Sprint Fidelis leads to hospitals and physicians, knowing that they would be thereby sold to patients with heart diseases and disorders (including Plaintiff and Class members) and implanted in those patients.

82. Medtronic's Sprint Fidelis leads were expected to and did reach Plaintiff and the Class without substantial change in their condition as manufactured and sold by Medtronic. In light of the defects described herein, at the time the leads reached Plaintiff and the Class, they were in a condition not contemplated by any reasonable person among the expected users of the devices, and were unreasonably dangerous to the expected users of the devices when used in reasonably expectable ways of handling or consumption.

83. The Sprint Fidelis leads designed, manufactured, assembled, and sold by Medtronic to Plaintiff and Class members were in a defective condition unreasonably dangerous to any user or consumer of the devices, and Plaintiff and Class members were, and are, in the class of persons that Medtronic should reasonably have foreseen as being subject to the harm caused by the devices' defective condition.

84. Plaintiff and Class members used the leads in the manner in which the leads were intended to be used. This has resulted in injuries to Plaintiff and Class members.

85. Neither Plaintiff nor Class members were aware of, and could not in the exercise of reasonable care have discovered, the defective nature of Medtronic's Sprint Fidelis leads. Nor could they have known that Medtronic designed, manufactured or assembled the leads in a manner that would increase the risk of bodily injury to Plaintiff and the Class.

86. As a direct and proximate result of Medtronic's design, manufacture, assembly, marketing and sales of the Sprint Fidelis leads, Plaintiff and the Class members have sustained and will continue to sustain severe emotional distress, the need for an expense of ongoing medical monitoring, economic losses and consequential damages, and are therefore entitled to compensatory relief according to proof, and entitled to a declaratory judgment that Medtronic is liable to them for breach of its duty to Plaintiff and the Class members and its failure to provide a safe and effective medical device. Plaintiff and the Class members are also entitled to equitable relief as described below.

87. Medtronic's Sprint Fidelis leads constitute a product dangerous for its reasonably intended use due to defective design, manufacture, assembly and marketing. Medtronic is therefore liable to Plaintiff and Class members to pay the costs of a court-supervised medical monitoring program to detect fractured or malfunctioning leads before they cause further injury and damage in an amount according to proof.

SECOND CLAIM FOR RELIEF
(Breach of Implied Warranty)

88. Plaintiff, on behalf of himself and all others similarly situated, re-alleges and incorporates the allegations contained in the foregoing paragraphs.

89. Medtronic impliedly warranted that its Sprint Fidelis leads, which Medtronic designed, manufactured, assembled, promoted and sold to Plaintiff and Class members, were merchantable and fit and safe for ordinary use. Medtronic further impliedly warranted that its Sprint Fidelis leads were fit for the particular purpose of providing prophylactic treatment of patients with a variety of medical issues, including prior myocardial infarction and a limited ejection fraction, spontaneous and/or inducible life-threatening ventricular arrhythmias and a high risk for developing such arrhythmias.

90. Medtronic further impliedly warranted that its Sprint Fidelis leads were based on "proven" lead technology and that the Sprint Fidelis leads were easier to implant than others.

91. Medtronic's Sprint Fidelis leads were defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiff and Class members to the threat of severe and permanent injuries and death. Therefore, Medtronic breached the implied warranties of merchantability and fitness for a particular purpose when its leads were sold to Plaintiff and Class members, in that the leads are defective and have fractured and will, more likely than not, fail to function as represented and intended.

92. As a direct and proximate result of Medtronic's breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiff and Class members have sustained and will continue to sustain severe emotional distress, the need for and expense of ongoing medical monitoring, economic losses and consequential damages, and are therefore entitled to compensatory damages and equitable relief according to proof.

THIRD CLAIM FOR RELIEF
(Negligence)

93. Plaintiff, on behalf of himself and all others similarly situated, re-alleges and incorporates the allegations contained in the foregoing paragraphs.

94. Medtronic had a duty to Plaintiff and Class members to provide a safe product in design and manufacture, to notify the FDA of design flaws, and to warn the FDA and Class members of the defective nature of the Sprint Fidelis leads. Medtronic breached its duty of reasonable care to Plaintiff and Class members by incorporating a defect into the design of the Sprint Fidelis leads, thereby exposing Plaintiff and Class members to severe physical injury or death, and causing severe emotional distress, economic injury and the need for and expense of ongoing medical monitoring, as well as other injury.

95. Medtronic breached its duty of reasonable care to Plaintiff and Class members by manufacturing and assembling the Sprint Fidelis leads in such a manner that they were prone to fracture, to fail to operate and to malfunction, thereby exposing Plaintiff and Class members to life-threatening physical trauma.

96. Medtronic breached its duty of reasonable care to Plaintiff and Class members by failing to notify the FDA, physicians, the Plaintiff and the Class members at the earliest possible date of known design defects in the leads.

97. Medtronic breached its duty of reasonable care to Plaintiff and Class members by failing to exercise due care under the circumstances.

98. As a direct and proximate result of Medtronic's negligent breach of its duty of care owed to Mr. Hunter and the Class members, Mr. Hunter and the Class members are currently exposed to a defective product which threatens them with severe physical injury and death.

99. Plaintiff and the Class members have a serious and reasonable fear, which stems from knowledge corroborated by reliable medical and/or scientific opinion, that they more likely than not will suffer severe physical injury or death in the future as the result of the implantation of the defective Sprint Fidelis leads.

100. As a direct and proximate result of the carelessness and negligence of Medtronic as set forth in the preceding paragraphs, Plaintiff and Class members have sustained and will continue to sustain severe emotional distress, the need for and expense of ongoing medical monitoring, economic losses and other damages, and are entitled to compensatory damages and equitable and declaratory relief according to proof. Medtronic's egregious misconduct alleged above also warrants the imposition of punitive damages against Medtronic.

FOURTH CLAIM FOR RELIEF
(Negligent Infliction of Emotional Distress)

101. Plaintiff, on behalf of himself and all others similarly situated, re-alleges and incorporates the allegations contained in the foregoing paragraphs.

102. Medtronic carelessly and negligently manufactured, marketed and sold defective Sprint Fidelis leads to Plaintiff and Class members, carelessly and negligently concealed these defects from Plaintiff and Class members, and carelessly and negligently misrepresented the quality, safety and usefulness of the leads.

103. Medtronic had a duty to Plaintiff and Class members to provide a safe product in design and manufacture, to notify the FDA of design flaws, and to warn the FDA and Class members of the defective nature of the Sprint Fidelis leads. Medtronic breached its duty of reasonable care to Plaintiff and Class members by incorporating a defect into the design of the Sprint Fidelis leads, thereby causing Plaintiff's and Class members' injuries.

104. Medtronic breached its duty of reasonable care to Plaintiff and Class members by manufacturing and assembling the Sprint Fidelis leads in such a manner that they were prone to fracture and fail to operate and malfunction and expose Plaintiff and Class members to life-threatening physical trauma.

105. Medtronic breached its duty of reasonable care to Plaintiff and Class members by failing to notify the FDA, physicians, the Plaintiff and the Class members at the earliest possible date of known design defects in the leads.

106. Medtronic breached its duty of reasonable care to Plaintiff and Class members by failing to exercise due care under the circumstances.

107. As a direct and proximate result of Medtronic's negligent breach of its duty of care owed to Mr. Hunter and the Class members, Mr. Hunter and the Class members are currently exposed to a defective product which threatens them with severe physical injury and death.

108. Plaintiff and the Class members have a serious and reasonable fear, which stems from knowledge, corroborated by reliable medical and/or scientific opinion, that they more likely than not will suffer severe physical injury or death in the future as the result of the implantation of the defective Sprint Fidelis leads.

109. Plaintiff and Class members were directly involved in and directly impacted by Medtronic's carelessness and negligence, in that Plaintiff and Class members have sustained and will continue to sustain severe emotional distress, economic losses, the need for and expense of ongoing medical monitoring and other damages as a direct result of the decision to purchase, use and have implanted in their bodies a defective and dangerous product manufactured, sold and distributed by Medtronic.

110. Medtronic's misconduct as alleged above has caused Plaintiff and Class members to suffer severe emotional trauma and long continued emotional disturbance. Plaintiff and Class members are therefore entitled to compensatory damages and equitable and declaratory relief according to proof.

FIFTH CLAIM FOR RELIEF
(Breach of Express Warranties)

111. Plaintiff, on behalf of himself and all others similarly situated, re-alleges and incorporates the allegations contained in the foregoing paragraphs.

112. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, the internet, and other communications intended for medical patients, and the general public, that the defective leads were safe, effective, fit and proper for their intended use.

113. In allowing the implantation of the defective leads, Plaintiff relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the defective leads were not safe and were unfit for the uses for which they were intended.

114. Through its sale of the defective leads, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

115. Any disclaimers of express warranties are ineffectual as they were not provided to Plaintiff or the Class members or otherwise made known totem. In addition, any such disclaimers are unconscionable.

116. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and the Class members have sustained economic losses, the need for and expense of ongoing medical monitoring and other damages for which he is entitled to compensatory damages in an amount to be proven at trial. Any disclaimer of consequential damages is invalid as the limited remedy provided fails in its essential purpose to redress the harm and damages to Plaintiff and the Class members in that it, in effect, provides no remedy at all for the defect necessary to be redressed. In addition, any such disclaimer of consequential

damages in unconscionable. Defendants are liable to Plaintiff and the Class members jointly and severally for all declaratory, equitable and injunctive relief, including the costs of a court-supervised medical monitoring program, and for all damages to which Plaintiff is entitled by law.

FIFTH CLAIM FOR RELIEF
(Violation of Unfair Competition Law ("UCL"), Bus. & Prof. Code §§ 17200, *et seq.*)

117. Plaintiff, on behalf of himself and all others similarly situated, realleges and incorporates the allegations contained in the foregoing paragraphs

118. The UCL prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising" as that term is used in Business and Professions Code § 17500.

119. In violating the California Business and Professions Code §§ 17200, *et seq.*, as set forth above as the Fifth Cause of Action and incorporated herein, Medtronic engaged in unlawful business practices in violation of the UCL.

120. Medtronic engaged in unfair business practices in violation of the UCL. The benefits of its practice of selling defective Spirit Fidelis leads that are inherently dangerous and unreasonably prone to malfunction are outweighed by the resulting harm and danger to Plaintiff, the Class, and the public.

121. Medtronic engaged in fraudulent business acts or practices in that it actively concealed material information about the safety of the defective Spirit Fidelis leads and it engaged in marketing which was likely to deceive the Plaintiff, the Class, physicians and the public.

122. Medtronic engaged in unfair competition or unlawful, unfair or fraudulent business practices in violation of the UCL when it represented, through its marketing, warranties and other express representations that the defective Spirit Fidelis leads were safe and free from defects.

123. As a proximate result of its unlawful, unfair or fraudulent practices, Medtronic has been unjustly enriched and should be required to make restitution and/or disgorgement of profits unjustly earned to the Plaintiff and the Class pursuant to Sections 17203

and 17204 of the UCL and/or provide other appropriate equitable relief, including a court-supervised medical monitoring program.

SIXTH CLAIM FOR RELIEF
(Declaratory Relief and Medical Monitoring)

124. Plaintiff, on behalf of himself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

125. Plaintiff and Class members have no adequate remedy at law and damages cannot adequately compensate Plaintiff and Class members for the injuries suffered and threatened, rendering declaratory, injunctive, and other equitable relief appropriate.

126. Through the unlawful conduct set forth in the preceding paragraphs, Plaintiff and thousands of Class members have been implanted with a device which tends to fracture, and otherwise malfunction. These defects have potentially fatal consequences for many patients who rely upon the presence of the leads connected to the ICDs to regulate their cardiac rhythms. These defects place Plaintiff and Class members at significant, increased risk of injury and death, as a direct result of their implantation with said leads, through Defendants' fault. These risks are unique to the Class, and detectable and correctable through ongoing medical monitoring.

127. There are medical risks to Plaintiff and Class members associated with having the defective Sprint Fidelis leads explanted, as they have been implanted directly onto the heart wall. Explanation procedures expose Plaintiff and Class members to significant risks attendant to surgery, not least of which are potentially life-threatening infections and other harm.

128. At the same time, Plaintiff and Class members, along with their physicians, must weigh these risks against the possibility that Medtronic's Sprint Fidelis leads will fail or have failed to function as designed, represented and intended, resulting in an increased risk of heart damage, failure and/or death.

129. Accordingly, Plaintiff, on behalf of himself and all others similarly situated, requests the following classwide equitable relief:

(a) That Medtronic be ordered to notify all potential Class members of the defective nature of the Sprint Fidelis leads;

(b) That Medtronic be ordered to create a treatment fund, under the continuing jurisdiction and supervision of this Court, to monitor the health of Plaintiff and Class members, and to pay or reimburse Plaintiff and Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses caused by Medtronic's wrongdoing; and

(c) Declaratory judgment that Medtronic is liable to Plaintiff and all Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Medtronic's wrongdoing.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and all others similarly situated, prays for judgment against Medtronic as follows:

1. For an Order certifying the Class and any appropriate subclasses thereof under the appropriate provisions of Federal Rule of Civil Procedure 23, and appointing Plaintiff and his counsel to represent the Class;

2. For the equitable relief requested;

3. For compensatory damages according to proof;

4. For punitive or exemplary damages against Medtronic, consistent with the degree of Medtronic's reprehensibility and the resulting harm or potential harm to Plaintiff and the Class, and in an amount sufficient to punish Medtronic and deter others from similar wrongdoing;

5. For all applicable statutory damages under the consumer protection legislation of the State of California;

6. For declaratory judgment that Medtronic is liable to Plaintiff and Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Medtronic's wrongdoing;

7. For notice to be disseminated to all Class members who have been implanted with Sprint Fidelis leads;

8. For a restitution and disgorgement of profits;

9. For an award of attorneys' fees and costs;

10. For prejudgment interest and the costs of suit; and

11. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff Rashid Hunter, on behalf of himself and all other California state residents and citizens similarly situated, hereby demands a trial by jury in this case as to such issues so triable.

Dated: December 26, 2007

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

By: _____
Elizabeth J. Cabraser

Elizabeth J. Cabraser
ecabraser@lchb.com
275 Battery Street, 30th Floor
San Francisco, CA 94111-3339
Telephone: (415) 956-1000
Facsimile: (415) 956-1008

Wendy Fleishman
wfleishman@lchb.com
LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
780 Third Avenue, 48th Floor
New York, NY 10017
Telephone: (212) 355-9500
Facsimile: (212) 355-9592

Elizabeth A. Alexander
ealexander@lchb.com
LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
150 Fourth Ave., N., Suite 1650
Nashville, TN 37219
Telephone: (615) 313-9000
Facsimile: (615) 313-9965

Attorneys for Individual and Representative Plaintiff